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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/999,752	06/04/1997	FIONA CATHERINE MILLAR	TEVNHC 3.0-200	4312
530 7590 10/07/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER				
TRAN, SUSAN T				
ART UNIT		PAPER NUMBER		
1615				
MAIL DATE		DELIVERY MODE		
10/07/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

08/999,752

**Applicant(s)**

MILLAR, FIONA CATHERINE

**Examiner**

S. Tran

**Art Unit**

1618

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No./Mail Date: \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/20/08 has been entered.

### ***Claim Objections***

Claim 23 is objected to because of the typographical error. The limitation "reprocotrol" in line 10, should read "reproterol".

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. It appears that the present specification does not

provide support for the limitation "an actuator with a gray orifice aperture of from about 100 to about 300 microns, wherein said canister fits into the actuator".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the phrase "bronchodilator selected from the group consisting of...tolubutrol and orciprenaline or a salt thereof", a fluorocarbon propellant, and 6% to 25% of a polar co-solvent, it is not entirely clear which if all the above disclosed components are part of the Markush group. Further the limitation "or salt thereof" after "orciprenaline" is not clear whether the salt is referring to just the orciprenaline or for the entire bronchodilators in the Markush group.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz WO 93/11747, in view of Schultz et al. US 5,899,201.

Schultz '747 teaches a suspension aerosol formulation in which the drug is in particulate form (page 5) and the fluorocarbon propellant is HFC 134a or HFC 227 (page 3). Page 5, lines 27-31 teach that the formulation does not need additional components. Page 9 teaches that ethanol can be optionally included to about 20% and the surfactant is also optional. Example 8 discloses a canister containing the pirbuterol acetate, HFC 227 and ethanol at 10% without a surfactant. Preferred drug for use in the formulation includes formoterol (page 7, 3<sup>rd</sup> paragraph).

Schultz '747 does not teach the claimed actuator.

Schultz '201 teaches an actuator for use in connection with medicinal aerosol formulations. The actuator comprises housing 13 adapted to receive and support aerosol canister containing a medicinal aerosol formulation, a metered dose valve, and an exit orifice with size from about 0.25 mm (250  $\mu$ m) (abstract; and column 3, lines 5 through column 4, lines 1-21). Thus, it would have been obvious to one of ordinary skill in the art to modify the aerosol canister of Schultz '747 to include the actuator in view of the teachings of Schultz '201, because Schultz '201 teaches compared to a conventional actuator, the actuator of Schultz '201 is capable of delivering a dose of drug in the form of an aerosol such that more drug reaches the area of the lung where it is therapeutically effective, and less drug is deposited in the mouth and throat, thus decreasing undesired systemic effects of the drug.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz WO 93/11747, in view of Schultz et al. US 5,899,201 and Greenleaf et al. US 5,348,730.

Schultz is relied upon for the reason stated above. Schultz does not explicitly teach salbutamol as the bronchodilator.

Greenleaf teaches bronchodilator such as epinephrine, phenylepinephrine, and salbutamol (column 5, lines 17-30). Thus, it would have been obvious to one of ordinary skill in the art to include sabutamol in the suspension formulation of Schultz, because Greenleaf teaches sabutamol is a known bronchodilator among other bronchodilators, and because Schultz teaches a suspension aerosol formulation suitable for a wide variety of bronchodilators.

### ***Response to Arguments***

Applicant's arguments filed 06/20/08 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's arguments filed 06/20/08, the 102(b) rejection by Schultz has been withdrawn.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/  
Primary Examiner, Art Unit 1618